EXPRESS MAIL LABEL NO .: EV668788605US DATE: September 29, 2006

IAP13 Rec'd PCT/PTO 29 SEP 2006

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

ATTORNEY'S DOCKET NUMBER **TEVNHC 3.3-066**

vn (see 37 CFR 1.5) \$190719V94V8 **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371** INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/US2005/017292 17 May 2005 17 May 2004 TITLE OF INVENTION HEAT STERILIZATION OF GLUCOCORTICOSTEROIDS APPLICANT(S) FOR DO/EO/US Adrian Ashley, Paul Lamb, Donald McDonald, John Miller, Martin J. Oliver, and Mathew Pollard Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). 5. x A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. b. x is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). 7. X Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. d. x have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). An English language translation of the annexes of the International Preliminary Examination Report under PCT 10. Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. x An Information Disclosure Statement under 37 CFR 1.97 and 1.98. w/SB-08 (0 enclosed) An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. х A preliminary amendment. 14. x An Application Data Sheet under 37 CFR 1.76. A substitute specification. 16. A power of attorney and/or change of address letter. 17 A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 18. x A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

IAP5 Rec'd PCT/PTO 29 SEP 2006

PTO-1390 (Rev. 07-2005)
Approved for use through 03/31/2007. OMB 0651-0021
U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Pagerwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION OF (III 1944 861			861	INTERNATIONAL APPLICATION NO. PCT/US2005/017292		ATTORNEY'S DOCKET NUMBER TEVNHC 3.3-066			
20. X Other items or information: Return Receipt Postcard									
The fellowing face have been submitted.									
The following fees have been submitted 21. x Basic national fee (37 CFR 1.492(a))						\$ 300.0			
21. X Basic national fee (37 CFR 1.492(a))									
22. x Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report									
prepared by II	PEA/US ir	\$ 200.0							
All other situation	prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)\$0 \$ 200.00 \text{All other situations}								
23. x Search fee (37 CFR 1.492(b))									
If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)									
Search fee (37 C Internation		\$ 400.0	ا ا						
International Sea	rch Repo								
All other situation		 	·						
TOTAL OF 21, 22 and 23 =						\$ 900.0	0		
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.									
Total Sheets	Extra Sh	ttra Sheets Number of each additional 50 or fraction thereof (round up to a whole number)							
29 - 100 =	29 - 100 = /50 =		x \$250.00		\$				
Surcharge of \$13 after the date of		\$							
CLAIMS NUI		NUM	ABER FILED NUMBER EXTRA RATE						
		9-20 = 0 x 50.00		0.0					
Independent claims		3 - 3 = 0 x 200.00		0.00					
MULTIPLE DEPENDENT CLAIM(S) (if applicable) + 360.00					360.00				
TOTAL OF ABOVE CALCULATIONS = \$ 1,260.00									
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.									
		\$ 1,260.0	0						
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).									
		\$ 1,260.00							
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property \$									
\$									
TOTAL FEES ENCLOSED =						\$ 1,260.00			
· . I						Amount to be refunded:	\$		
						Amount to be charged	\$		
		-,-							



10/594861

PTO-1390 (Rev. 07-2005)
Approved for use through 03/31/2007. OMB 0651-0021
U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

a. A check in the amount of \$ to cover the	ne above fees is enclosed.							
b. X Please charge my Deposit Account No. 12-1095 in t A duplicate copy of this sheet is enclosed.	he amount of \$1,260.00 to cover the above fees.							
c. X The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 12-1095 . A duplicate copy of this sheet is enclosed.								
d. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038								
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed an granted to restore the International Application to pending status.								
SEND ALL CORRESPONDENCE TO:	SIGNATURE P. Foly							
	SIGNATURE /							
	Shawn P. Foley							
CUSTOMER NUMBER: 000530	TV WILE							
COSTOMER NUMBER. 000330	33,071							
	REGISTRATION NUMBER							